

## REMARKS

The requisite fee of \$1,115.00 for a five-month extension of time may be charged to Deposit Account No. 02-1818. Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 02-1818. If a Petition for Extension of Time is needed, this paper is to be considered such Petition.

Claims 1-11, 13-17, 19-29 and 31-37 are pending. Claims 1, 5, 6 and 10 are amended for clarity. Claim 8 is amended to correct a typographical error. No new matter is added.

## TRAVERSAL OF RESTRICTION REQUIREMENT

### Traverse of finding of lack of unity

The Office Action restricts the pending claims into three groups as follows:

- I: Claims 1-11, drawn to a biphasic culture medium;
- II: Claims 13-17, drawn to a kit including the biphasic culture medium; and
- III: Claim 19-29 and 31-37, drawn to a method of detecting protozoa.

The Examiner, recognizing that the rules of unity of invention under PCT Rule 13.1 apply to the instant case, urges that there is a lack of unity because the three groups allegedly do not relate to a single inventive concept. This conclusion is based upon the premise that the special technical feature between the groups, the biphasic culture medium, is disclosed in Clark *et al.* (Clin Microbiol Reviews 15: 329-341 (2002)).

Reconsideration of the Requirement respectfully is requested in view of the amendments herein and the following remarks. As noted, the claims are amended to render it clear that the liquid phase contains three specified ingredients and one optional ingredient. Hence, the medium, as discussed below, is novel over the cited art, rendering it a novel technical feature shared among all claims. Therefore, all pending claims are unified.

Independent claim 1 of Group I is directed to:

*A bi-phasic culture medium, comprising:  
a solid phase containing an egg slope or agar slope; and  
a liquid phase consisting essentially of a serum, a peptone, a phosphate  
buffered saline and optionally an antibiotic.*

Claim 13 of Group II is directed to:

*A kit, comprising:  
a container containing the medium of claim 1; and  
a container containing rice starch.*

Claim 19 of Group III is directed to:

*A method of detecting the presence of protozoa in a specimen, the  
method including:*

*adding to the medium of claim 1, the specimen, rice starch and where necessary, an antibiotic;  
allowing the medium to incubate for a time period so as to cultivate protozoa; and  
examining at least a portion of the incubated medium to detect the presence of protozoa.*

Claim 20 of Group III is directed to:

*A method of detecting protozoa in faecal matter, comprising:  
adding to the medium of claim 1 faecal matter, rice starch and where necessary, an antibiotic;  
allowing the medium to incubate for a time period so as to cultivate intestinal protozoa; and  
examining at least a portion of the incubated medium to detect the presence of the protozoa.*

#### **Disclosure of the Cited Art**

Clark *et al.* describes diphasic LE medium and diphasic Robinson's medium (see pages 332-333). The diphasic LE medium includes Locke's solution (an aqueous solution of sodium chloride, calcium chloride, potassium chloride, magnesium chloride, monobasic and dibasic sodium phosphate, sodium bicarbonate and monobasic potassium phosphate) as a liquid phase overlaying an egg slant (page 332). The LE medium optionally contains 20% human or horse serum in the liquid phase (page 334). Clark *et al.* also describes diphasic Robinson's medium, which is a complex medium that includes twelve ingredients. The preparation of Robinson's medium involves the preparation of six separate aqueous stock solutions: a). 0.5% erythromycin; b). 20% bactopectone; c). potassium hydrogen phthalate and sodium hydroxide; d). "R medium," which contains sodium chloride, citric acid, potassium phosphate monobasic, ammonium sulfate, magnesium sulfate and lactic acid; e). "BR medium," which is "R medium" as described in (d) inoculated with a live standard *E. coli* strain; and f). "BRS medium," which is "BR medium" as described in (e) to which an equal volume of heat inactivated bovine serum is added (see page 333). Aliquots of solutions a), b), c) and f) are combined to form a liquid phase, which is layered over an agar slant.

#### **Analysis**

The liquid phase in the instantly claimed media contain only three recited components and one optional component. In contrast, LE medium and Robinson's medium described in Clark *et al.* contain 8 and 12 recited components, respectively, in the liquid phase. Thus, the media as claimed are not disclosed in Clark *et al.* As noted above, the recited media are an element in every pending claim. Thus, the media can serve as a novel technical feature

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**Election and Preliminary Amendment**

unifying all pending claims. Therefore, all pending claims (*i.e.*, Groups I-III) are unified and should be examined in this application.

#### **REQUIREMENT FOR ELECTION OF SPECIES**

The Office Action states that

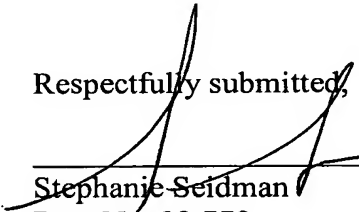
Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

It is unclear to Applicant whether the Examiner intended to set forth a requirement for an election of species for search purposes. In an effort to be fully responsive and to advance prosecution, in the event the Action does require such election, Applicant has elected an egg slope as a species of the solid phase, horse serum as a species of serum and bactopectone as a species of peptone for search purposes.

\* \* \*

In view of the election, amendments and remarks herein, withdrawal of the restriction requirement, examination on the merits and allowance are respectfully requested.

Respectfully submitted,

  
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